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Fumarin: Pesticide Registration Standard

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Office of
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Washington DC 20460

September 1980

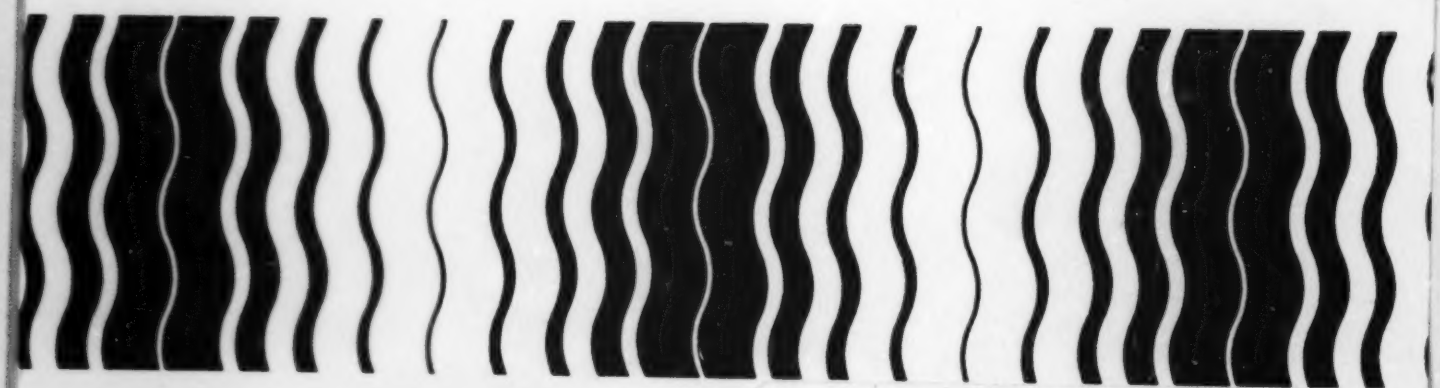
Pesticides

EPA

3-(alpha-acetonylfurfuryl) - 4-hydroxycoumarin)

Fumarin®

Pesticide Registration Standard



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REGISTRATION STANDARD

PRODUCTS CONTAINING FUMARIN AND THE SODIUM SALT OF FUMARIN

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CHAPTER 1

HOW TO REGISTER UNDER A REGISTRATION STANDARD

Organization of the Standard
Purpose of the Standard
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"Product Specific" Data and "Generic" Data
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Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

> "(A) its composition is such as to warrant the proposed claims for it;
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a 'product by product' basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there

was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the 'product by product' approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.
Second, over the years, as a result of inevitable and continuing advancesin scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the 'product by product' approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or re-registration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a

product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

Requirement to Re-register Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to re-register all currently registered products as expeditiously as possible. Congress also agreed that re-registration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for re-regisration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for re-registration set forth in the Guidance Package which accompanies this Standard.

"Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29686, July 10, 1978, and 43 FR 37336, August 22, 1978), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the second chapter.)

The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that is "product specific," i.e., data that relates only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

(B) "generic" data that pertains to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or re-registration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert," ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he re-registers his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, re-registration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which is described by all the following criteria:

(1) the data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;
(2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for re-registration, or to support or maintain in effect an existing registration;
(3) the data are relevant to the Agency's decision to register or re-register the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);
(4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and
(5) the data are not those for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for re-registration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which arespecific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or re-registration of a manufacturing-use product, and each applicant for registration or re-registration of an end-use

product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for re-registration (or new registration) under this Standard is found in the Guidance Package for this Standard.

Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in its summary second chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a 'product by product' basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of re-registering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether that data in question is "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

CHAPTER 2

REGULATORY POSITION

This chapter presents the Agency's decision on what standards of product composition, toxicity, use, labeling, and packaging are required for the pesticide active ingredients in question. The decision complies with the rules and regulations (40 CFR 162) used to implement the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), and with the Agency's present regulatory policies. There are different requirements for manufacturing-use chemicals and for each type of end-use formulation which present a significantly different set of hazards. This Registration Standard is based upon all data and information on Fumarin® * and its Sodium Salt available to the Agency's reviewers as of August, 1979.

REGULATORY DECISION

The Agency has reviewed the data available to it on Fumarin and the Sodium Salt of Fumarin. As will be indicated in the Topical Discussions which follow, scientific data on Fumarin products are almost entirely absent. Based on the uses of this rodenticide, however, the Agency believes that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations would be met or exceeded for Fumarin. Fumarin products currently registered, therefore, may be re-registered subject to conditions imposed for filling the data gaps and the label modifications which have been identified. When these data requirements are filled, the Agency will reassess the registration status of Fumarin products.

CRITERIA FOR REGISTRATION UNDER THE STANDARD

1. Product Composition

   In order to be covered under this Standard, technical Fumarin, Fumarin Sodium Salt, and their diluted products must comply with the following standards. All products must contain Fumarin (3-(alpha-acetonyl-furfuryl)-4-hydroxycoumarin) or its Sodium Salt as an active ingredient (a.i.). The Agency expects technical Fumarin to be 98% a.i. Should an applicant desire to register any products that depart from those covered by this standard, that applicant should contact the Agency for specific directions on how to register those

* Fumarin® is a registered trade name of Amchem Products, Inc. Its use in this document does not constitute endorsement or recommendation for use by this Agency. Since there is no acceptable common name for this compound, the trade name will be used in this document for convenience.

products. The acute toxicology testing on technical Fumarin and technical Fumarin Sodium Salt must demonstrate into which Toxicity Categories (I through III) the products fall for the following acute effects:

Acute Oral Toxicity;
Acute Dermal Toxicity;
Acute Inhalation Toxicity;
Primary Eye Irritation; and
Primary Dermal Irritation.

2. Labeling

Labels for currently registered manufacturing-use Fumarin products must include the following:

The intended end-use of products formulated from technical and concentrated products determine which data the applicants for (re) registration of the manufacturing-use product are required to submit or cite. All technical and concentrated products must therefore carry one of the following statements on the label:

(1) For Formulation Into End-Use Rodenticide Products Intended Only for Domestic, Non-Food Use;

(2) For Formulation Into End-Use Rodenticide Products Intended Only for Non-Domestic, Non-Food Use;

(3) For Formulation Into End-Use Rodenticide Products Intended Only for Non-Domestic, Non-Food Use excluding dumps; or

(4) For Formulation Into End-Use Rodenticide Products Intended Only for Domestic or Non-Domestic, Non-Food Use.

3. Data Gaps

Additional testing is a condition for the reregistration of all currently registered Fumarin and Fumarin Sodium Salt products. Under Section 3(c)(2)(B)(ii) of FIFRA, as amended, current registrants of Fumarin and Fumarin Sodium Salt products must agree to develop the required data within 90 days of being notified of these standards in order to remain eligible for reregistration. Anyone wishing to register new Fumarin and Fumarin Sodium Salt products or anyone wishing to receive Federal registrations for products which are currently registered in one or more of the states at the time these standards are published, must agree to provide the required testing or to share in the cost of developing the data as a condition of registration under 3(c)(7) and 3(c)(1)(D). In addition, registrants

of new products must offer compensation for all applicable data used to set the standards listed below which were submitted to the Agency after December 31, 1969, as provided in Section 3(c)(1)(D) of FIFRA.

The data needed to support the reregistration of formulations of Fumarin and its Sodium Salt are tabulated according to discipline in the Tables which follow.

These requirements are based on a review of the limited scientific data available on Fumarin and the use pattern and methods of formulations of Fumarin products. Most of the product chemistry data decribed in 43 FR, No. 132, Part 163.61-2 are required by the Agency to characterize Fumarin and its Sodium Salt and to determine its environmental and health hazards. Environmental Fate data are not being required because of the use pattern of Fumarin and its Sodium Salt, the limited poundage that is available and the small chance of residues being found in soil or water. The Agency is requiring a label modification, however, to reduce any potential hazard. Toxicology data are being required, in most cases, for Technical Fumarin and the 0.5% Fumarin concentrate only because currently registered formulations of Fumarin are substantially similar in composition and are formulated with natural ingredients as inerts. In addition, while the Agency expects some exposure, such exposure is likely to be low in most cases.

Ecological Effects data are not required so long as the registrant modifies labels to require use with bait boxes and only in or around buildings and other structures and in transport vehicles (truck, planes, and ships). Available studies, although inadequate, suggest that Fumarin is at least highly toxic to wild mammals. Avian hazard can result from direct ingestion of baits and through secondary poisoning. Hazard to aquatic organisms and wildlife is expected to be minimal, however, because of the low volume of use and method of application. Thus, registrants may satisfy data requirements by modifying labels. Should registrants not wish to use required labeling, or should other significant uses be proposed, the Ecological Effects data discussed in Chapter 7 may be required unless a logical argument can be made which shows minimal expectation of exposure, and consequently, risk. Registrants who seek use in dumps on their labeling must specifically address non-target effects by either submitting data or demonstrating to the Agency that use patterns are such as to preclude unreasonable exposure. In addition, these studies may be required to support the continued registration of these products if total yearly production of Fumarin and its Sodium Salt reach 25,000 pounds.

PRODUCT CHEMISTRY

To be covered under this Standard, all applicants for registration or re-registration of Fumarin Products must agree to cite or submit the following information on the physical/chemical composition of the products.

Table 1 - Product Chemistry Data Gaps

Data Requirements (Data Gap)	Test Substances: Technical Fumarin	Technical Sodium Salt of Fumarin	Fumarin Formulating use products (concentrates)	End-Use Fumarin Formulated Products	End-Use Fumarin Sodium Salt Formulated Products
A. Disclosure of ingredients (Sec. 163.61-3(c))	R	R	R	R	R
B. Description of Manufacturing process (Sec. 163.61-4)	R	R	R	R	R
C. Discussion of Unintentional Ingredients (Sec 163.61-5)	R	R	R	NR	NR
D. Certification of Limits of a.i. (Sec. 163.61-6(b))	R	R	R	R	R
E. Product analytical methods and data for impurities (Sec. 163.61-7)	R	R	R	NR	NR
F. Physical and chemical properties (Sec. 163.61-8)	Below	Below	Below	Below	Below
1. Color	S	R	NR	R	R
2. Odor	S	R	NR	R	R
3. Melting point	S	R	NR	NR	NR
4. Solubility	R	R	NR	NR	R
5. Stability	S	R	NR	NR	NR
6. Octanol/water partition coefficent	R	R	NR	NR	NR
7. Physical state	S	R	R	R	R
8. Density or specific gravity	R	R	R	R	R
9. Boiling point	R	R	R	R	NR
10. Vapor pressure	R	R	R	R	NR
11. pH	R	R	R	R	R
12. Storage stability	R	R	R	R	R
13. Flammability	R	R	R	R	R
14. Oxidizing or reducing action	NR	NR	R	R	R
15. Explosiveness	NR	NR	R	R	R
16. Corrosion characteristics	R	R	R	R	R

LEGEND

R = Required, NR = Not Required, S = Submitted and in Agency files

TOXICOLOGY

To be covered under this Standard, all applicants for registration or re-registration of Fumarin Products must agree to cite or submit the following information on the Toxicity of the products.

Table 2 - Toxicology Data Gaps

Data Requirements (Data Gap)		Test Substances: Technical Fumarin	Fumarin 50% and 10% and Technical Sodium Salt of Fumarin	Fumarin 0.5% Formulating (concentrates)	End-Use Fumarin Formulated Products	End-Use Fumarin Sodium Salt Formulated Products
1. Acute Oral LD_{50}.....	163.81-1	R	NR_2	R	NR	NR
2. Acute Dermal LD_{50}.....	163.81-2	R	R^2	R	NR	NR
3. Acute Inhalation LC_{50}...	163.81-3	R	NR	R	NR	NR
4. Primary Eye Irritation.....	163.81-4	R	NR	R	R_1	NR
5. Primary Dermal Irritation..	163.81-5	R	NR	R	NR	NR
6. Dermal Sensitization.....	163.81-6	R	NR	R	NR	NR
7. Subchronic Oral.....	163.82-1	NR	NR	NR	NR	NR
8. Subchronic Dermal.....	163.82-2	R	NR	NR	NR	NR
9. Subchronic Inhalation.....	163.82-4	NR	NR	NR	NR	NR
10. Teratology.....	163.83-3	R	NR	NR	NR	NR
11. Mutagenicity	163.84-1, -2, -3, and 4	R	NR	NR	NR	NR

LEGEND

R = Required
NR = Not required. Extrapolations will be made from tests on the 98% Technical Fumarin
R_1 = Required on representative end-use bait formulations. Registrants will be notified individually.
R^2 = For the Technical Sodium Salt of Fumarin, this Study will be required unless a salt dissociation study shows that the sodium salt form readily dissociates under pH conditions.

ECOLOGICAL EFFECTS

To be covered under this Standard, all applicants for registration or re-registration of Fumarin Products must agree to cite or submit the following information on the Fish and Wildlife effects of the products.

Table 3 - Ecological Effects Data Gaps

Data Requirements (Data Gap)		Test Substances: Technical Fumarin	Technical Sodium Salt of Fumarin	Fumarin Formulating (concentrates)	End-Use Fumarin Formulated Products	End-Use Fumarin Sodium Salt Formulated Products
1. Single-Dose Oral LD_{50} ..... One Avian Species	163.71-1					
2. Subacute Dietary LC_{50} ..... One Waterfowl One Upland Game Bird	163.71-2					
3. Fish 96 Hour LC_{50} ..... One Coldwater One Warmwater	163.71-1(c)(3)					
4. Aquatic Invertebrate ..... LC_{50}	163.72-2					
5. Dietary LC_{50} on ..... . Target Rodent Species	163.71-3					
6. Primary Dietary LC_{50} .... on Carnivores	163.71-3					
7. Secondary Toxicity Feed-... ing Study on Carnivores	163.70-1(c)					
8. Secondary Toxicity Feed-... ing Study on Raptors	163.70-1(c)					

Data listed in items #1-8 of this table will not be required to support use patterns covered by this Standard provided that: 1) labels are modified as outlined in this document; and 2) total yearly production for all uses does not reach 25,000 lbs. 3) Dump uses whether in bait boxes or not will require fish and wildlife studies listed in items 1-8 in this Table.

4. Additional Labeling Requirements

Much of the data needed to complete all the labeling requirements (40 CFR 162.10) and risk assessment requirements (Section 162.11) for Fumarin products do not now exist. However, until the data are submitted to complete this registration standard, the Agency will require registrants to update their labels according to current requirements. These requirements are found in Section 162.10, Subpart H (Label Development) of the Registration Guidelines (currently being drafted by the Agency), and in the format labels which are being supplied to the registrants.

Oral, dermal, and inhalation exposure may occur because of the type formulations (dust and liquid) of Fumarin products and the location and duration of placement of the baits. A review of Fumarin's methods of formulation and use patterns indicates that commercial applicators and formulators as well as other persons in contact with Fumarin products in and around homes and buildings, especially children, domestic animals, and wildlife, could be exposed if use directions are not followed explicitly. Thus, label modifications are required to reduce any hazards associated with Fumarin products and to provide the reader with labels that are more likely to be understood and followed.

Basically, the required labeling changes include clarifying the sites, pests, and methods of application; revising out-of-date precautionary and storage/disposal statements; and placing label text in a clear, readable format.

Labels must include the following precautionary statements:

a. Tamper proof bait boxes are required for both Fumarin solid and Sodium Salt of Fumarin liquid end-use baits which are used for outdoor and agricultural uses. For other uses, excluding dumps, tamper proof bait boxes are required or baits must be placed in areas inaccessible to children, pets, and non-target wildlife. Labels must state:

   1) For outdoor agricultural premises prepared baits must be placed in tamper proof bait boxes.

   2) For other uses, excluding dumps, prepared baits must be placed in tamper proof bait boxes, or in areas inaccessible to children, pets, and non-target wildlife.

   3) Baits and dead animals are to be picked up and disposed of properly, with care to

prevent baits and dead animals from getting into soil and/or water, including sewage.

b. The term, "around", for labeling purposes means within five (5) feet of exterior surfaces of buildings, and not in fields adjacent to buildings.

c. Avoid contamination of food and feedstuffs. Do not place baits in contact with food or feedstuff or on food handling surfaces.

d. Note to Physicians.

If swallowed by humans, domestic animals, or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such cases, intravenous and oral administration of vitamin K_1 combined with transfusion of fresh blood or fresh frozen plasma may be indicated as in the case of hemorrhage caused by overdoses of bishydroxycoumarin.

e. Formulators, commercial applicators, and mixers must wear protective clothing, including long sleeves and impermeable hand gloves and face masks when mixing and handling Fumarin products. Remove clothing and wash after handling.

f. For Manufacturing Use products, including Technical and Concentrates, do not discharge into lakes, streams, ponds, or public waters unless in accordance with an NPDES permit. For guidance contact your Regional Office of EPA.

The registrants of products containing Fumarin or its Sodium Salt must follow the appropriate labeling format provided by the Registration Division in the Guidance Package.

5. Efficacy Data Requirements

Because the efficacy of products containing Fumarin and its Sodium Salt is formulation specific, the Agency is not including these data as part of the standard. However, as part of each application for registration or re-registration, the registrant must submit or reference acceptable laboratory efficacy data supporting his/her product.

The following table summarizes the required laboratory efficacy tests that need to be submitted or referenced for each type of product:

Type	Description of Products	Numerical Designation of Test* 1.201	1.202	1.203	1.204
I	Technical & Concentrates Formulated into Registered Products			X	X
II	Concentrates Diluted into End Use Liquid Baits	X	X		
III	Concentrates Diluted into End Use Dry Baits			X	X
IV	Concentrates Diluted into Registered Baits			X	X
V	Ready-to-Use End Use Dry Baits			X	X

*The Registration Division will provide the registrants with a copy of the protocols applicable to their products and with a list of laboratories which do this type of testing. The types of testing required for efficacy are contained in EPA's Standard Test Methods for Anticoagulants, Revision 9, February 17, 1978. They are:

1.201 Standard Norway rat anticoagulant liquid bait efficacy laboratory test method.

1.202 Standard house mouse anticoagulant liquid bait efficacy laboratory test method.

1.203 Standard Norway rat anticoagulant dry bait efficacy laboratory test method.

1.204 Standard house mouse anticoagulant dry bait efficacy laboratory test method.

CHAPTER 3

PRODUCT CHEMISTRY

INTRODUCTION

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes, but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, and upper limits only for some unintentional ingredients. Subpart D (43 FR, No. 132, 29696, July 10, 1978) suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytic method.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. Data are needed concerning the identity and physical state of the active ingredient (e.g., melting and boiling point data, vapor pressure and solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g., flammability, corrosivity and storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

CHEMISTRY PROFILE

Fumarin^{R}, 3-(alpha-acetonylfurfuryl)-4-hydroxycoumarin, is a rodenticide which contains a minimum of 98% of the active ingredient in its technical form.

Technical Fumarin is an amorphous cream-colored powder with a very slight characteristic odor. It is stable at ambient temperature. Technical Fumarin is very slightly soluble in water and soluble in ethanol, methanol, isopropanol and acetone. The melting point range is from 121-123°C.

Technical Fumarin is a "manufacturing-use product" and is not registered for end uses in technical concentrations.

Amchem Products, Inc. a subsidiary of Union Carbide Agricultural Products Company, Inc., is the sole manufacturer of Technical Fumarin. End-use products are formulated as both Fumarin solid baits and Sodium Salt of Fumarin. All products contain Fumarin as the active ingredient, with no multiple active ingredient products registered. End-use formulations are registered both for household and agricultural and industrial site uses for the control of rats and mice.

There are no data available on the composition and percentages of inerts in the 50% and 10% Fumarin concentrates. In addition, no physical/chemical properties for these formulations were reported.

TOPICAL DISCUSSION

In accordance with each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' of July 10, 1978 (43 FR, NO. 132, Part 163.61-2), which explains the minimum data that the Agency requires in order to adequately assess a pesticide's Product Chemistry.

Data Gaps	Guidelines Section
Chemical Identity	163.61-3
Manufacturing Process	163.61-4
Percentages of Components in Pesticide Products	163.61-6
Product Analytical Methods and Data	163.61-7
Physical/Chemical Properties	163.61-8

1. Fumarin

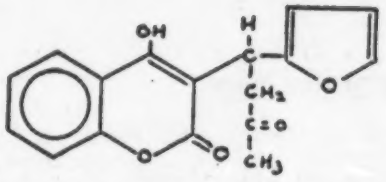
Chemical Identity

Fumarin is the trade name for 3-(alpha-Acetonylfurfuryl)-4-hydroxycoumarin. Other trade names that include the identical chemical compound as Fumarin are Coumafuryl, Coumarfuryl, Foumarin, Krumkil, Lurat, Ratafin and Rat-A-Way.

The technical chemical characterization for Fumarin follows:

Chemical Name:	3-(alpha-Acetonylfurfuryl)-4-hydroxycoumarin or 4-Hydroxy-3-[3-oxo-1-(2-furyl)butyl] coumarin
Molecular Weight:	298.28
Chemical Formula:	$C_{17}H_{14}O_5$
Type:	Rodenticide
Shaughnessey #:	086001
C.A.S. #:	117-52-2

Structural Formula:



Manufacturing Process

The manufacturing process for Fumarin as employed by Amchem Products, Inc., was not reported. This constitutes a data gap. However, a British patent [Spiess et al. 1955, 0500626] was granted covering a general process for the production of 3-substituted-4-hydroxycoumarins. This process could be used to show a methodology for producing Fumarin; but there is no certainty that this process is used by the manufacturer.

In this process, furfurylidene acetone, 4-hydroxycoumarin and trisodium orthophosphate in water are refluxed together for 4 hours. Upon cooling, the reaction mass is washed with water and dissolved in benzene. The benzene solution is filtered and purified by means of a diluted solution of alkali. Purification takes place by repeatedly dissolving the precipitate in alkali and precipitating with acid. The yield of this process is about 77%. No indication of the degree of purity is reported.

Percentages of Components in Fumarin Products

a. Technical Fumarin:

Technical Fumarin contains 3-(alpha-Acetonylfurfuryl)-4-hydroxycoumarin at 98% minimum concentration and inert ingredients at 2%. The confidential statement of formulas for the various Fumarin concentrates and ready to use products contain the technical Fumarin at the percentages indicated plus various inert ingredients. The identity of inert ingredients in these products will not be discussed but are contained in a "Confidential Statement of Formulas". However, the Agency gave full consideration to this information in developing the Registration Standard. The inert ingredients for Fumarin 50% and 10% concentrates were not included in the confidential statement of formulas. This constitutes a data gap.

b. Fumarin Solid Concentrates

a. 50% a.i.
b. 10% a.i.
c. 0.5% a.i.

c. Fumarin Solid Ready To Use

0.5% a.i.
0.025% a.i.

Product Analytical Methods and Data

A method for the analysis of Technical Fumarin [Segal, 1958, 00001200] has been submitted. In this procedure, a sample is extracted with ethylene dichloride. After extraction, decanting and centrifuging, a portion of the clear liquid is mixed with 1% NaOH solution. The alkali solution is decanted and the optical density is measured at 305 millimicrons using a Beckman Model DU Spectrophotometer. The reading is compared with a reading for a standard amount of Fumarin, and the amount present in the sample is calculated. While no validation data is offered, the method is regarded as adequate for the purpose of quantification. No means of positive identification is reported.

No infrared, ultraviolet or mass spectral data were submitted. No methods were reported for the analysis of the impurities in the technical material. This lack of analytical methods for impurities constitutes a data gap in the information needed to support this standard.

Physical/Chemical Properties.

The physical/chemical properties of Fumarin technical material [Amchem, no date, 00001199] are depicted as follows:

Color: cream-colored

Odor: very slight characteristic odor depending on the purity of the technical material

Melting Point: 121-123°C (pure 123-124°C)

Solubility:

water:	very slightly soluble
ethanol:	soluble
methanol:	soluble
isopropanol:	soluble
acetone:	soluble
benzene:	7.25 grams/100 grams solvent @ 26°C
Monochlorobenzene:	5.43 grams/100 grams solvent @ 26°C
Toluene:	4.02 grams/100 grams solvent @ 26°C
Ethylene dichloride:	15.4 grams/100 grams solvent @ 26°C
Chloroform:	26.7 grams/100 grams solvent @ 26°C
Carbon tetrachloride:	0.69 grams/100 grams solvent @ 26°C

Stability: completely stable at ambient temperature. Fumarin forms water-soluble salts with inorganic and organic bases.

Physical State: amorphous powder

Data were not submitted on the octanol/water partition coefficient, vapor pressure, pH, flammability corrosion characteristics. This missing information constitutes a data gap which will be addressed under the section, "Generic Data Gaps."

No physical/chemical properties data were submitted for any Fumarin formulation types. This constitutes a data gap for each type of formulation: Technical Fumarin and Fumarin Solid Concentrates; and Fumarin Solid Ready to Use.

2. Sodium Salt of Fumarin (for Liquid Use)

The Sodium Salt of Fumarin has been registered in formulations of solid concentrate for dilution in aqueous solutions. The active ingredients range from 0.14 percent to 1.20 percent in the formulations.

a. 1.20% a.i.
b. 0.50% a.i.
c. 0.14% a.i.

Chemical Identity

Data are not available on the chemical identity of the Sodium Salt of Fumarin. This constitutes a data gap.

Manufacturing Process

Data are not available on the manufacturing process of the Sodium Salt of Fumarin. This constitutes a data gap.

Percentages of Components in Sodium Salt of Fumarin

Data are not available on the percentages of components in the Sodium Salt of Fumarin. This constitutes a data gap.

Product Analytical Methods and Data

An analytical method for the determination of Sodium Salt of Fumarin in a technical material and formulation was submitted [Segal 1958, 00001200]. This analytical method is practically the same as the one for Fumarin with the following exception. Formulations containing Fumarin are extracted with ethylene dichloride; however, this extraction method is not applicable to the Sodium Salt of Fumarin because of the formation of emulsions of sodium hydroxide and ethylene dichloride. Consequently, the Sodium Salt of Fumarin is extracted from the sample with dry

acetone. The acetone is decanted, removed under vacuum, and the residue taken up with 1% sodium hydroxide. The absorption at 305 millimicrons is read on a Beckman Model D.U. Spectrophotometer and correlated with a standard curve to determine the Sodium Salt of Fumarin content. This procedure was checked and found to give recoveries of 99.7% and 99.8%. The sensitivity of the method is ca 1 mg of Fumarin/100 ml of 1% sodium hydroxide solution.

No methods were submitted for the quantification and identification of possible impurities in the technical material and formulations. This constitutes a data gap.

Physical/Chemical Properties

Except for an analytical method for the determination of the Sodium Salt of Fumarin, no other data pertaining to the Sodium Salt were submitted. Accordingly, none of the requirements stated in the Proposed Registration Guidelines of July 10, 1978 (43 FR, No. 132, Part 163.61-8) are satisfied and this deficiency constitutes a gap in the data base.

In addition, other registration requirements, i.e., identification of the compound, discussion of the manufacturing process, identification of impurities, discussion of inert ingredients, methodology for the analysis of the compound and its impurities, are also not satisfied. Consequently, for the (re)registration of the Sodium Salt of Fumarin, all of the above data (except the analytical method) are needed.

DISCIPLINARY REVIEW

Generic Data Gaps
Required Labeling

1. Generic Data Gaps

Assuming that the Sodium Salt of Fumarin's properties are different from Fumarin because of its more polar nature and coupled with the lack of any chemical data on this compound, all data requirements that are pertinent to its use are required. The data for Fumarin and Fumarin Sodium Salt as technical chemicals, concentrates (manufacturing use products) and end-use formulated products are required.

The data requirements identified in Table 1 are gaps in the product chemistry data base needed to adequately support a Registration Standard for Fumarin. Following each data requirement is listed the type formulation of Fumarin on which the Agency needs data. This data is described in the Proposed Registration Guidelines of July 10, 1978 (43 Fr, No. 132, Part 163.61).

2. Required Labeling

With the present data gaps, this Standard does not require changes in the current physical/chemical hazard labeling.

PRODUCT CHEMISTRY

To be covered under this Standard, all applicants for registration or re-registration of Fumarin Products must agree to cite or submit the following information on the physical/chemical composition of the products.

Table 4 - Product Chemistry Data Gaps

Data Requirements (Data Gap)	Test Substances: Technical Fumarin	Technical Sodium Salt of Fumarin	Fumarin Formulating use products (concentrates)	End-Use Fumarin Formulated Products	End-Use Fumarin Sodium Salt Formulated Products
A. Disclosure of ingredients (Sec. 163.61-3(c))	R	R	R	R	R
B. Description of Manufacturing process (Sec. 163.61-4)	R	R	R	R	R
C. Discussion of Unintentional Ingredients (Sec 163.61-5)	R	R	R	NR	NR
D. Certification of Limits of a.i. (Sec. 163.61-6(b))	R	R	R	R	R
E. Product analytical methods and data for impurities (Sec. 163.61-7)	R	R	R	NR	NR
F. Physical and chemical properties (Sec. 163.61-8)	Below	Below	Below	Below	Below
1. Color	S	R	NR	R	R
2. Odor	S	R	NR	R	R
3. Melting point	S	R	NR	NR	NR
4. Solubility	R	R	NR	NR	R
5. Stability	S	R	NR	NR	NR
6. Octanol/water partition coefficent	R	R	NR	NR	NR
7. Physical state	S	R	R	R	R
8. Density or specific gravity	R	R	R	R	R
9. Boiling point	R	R	R	R	NR
10. Vapor pressure	R	R	R	R	NR
11. pH	R	R	R	R	R
12. Storage stability	R	R	R	R	R
13. Flammability	R	R	R	R	R
14. Oxidizing or reducing action	NR	NR	R	R	R
15. Explosiveness	NR	NR	R	R	R
16. Corrosion characteristics	R	R	R	R	R

LEGEND

R = Required, NR = Not Required, S = Submitted and in Agency files

CHAPTER 1

ENVIRONMENTAL FATE

USE PROFILE

This registration standard covers Federally registered uses of Fumarin, 3-(alpha-Acetonylfurfuryl)-4-hydroxycoumarin, and its Sodium Salt. The Environmental Protection Agency (EPA) has registered these products as single active ingredients in different concentrations and formulations. The registrations are grouped into five different label types for both Fumarin and the Sodium Salt of Fumarin. This section describes current label use directions; changes in these directions have been dictated in Chapter II.

Type	Description of Products	Percentages
I	Technical and Concentrates Formulated into Registered Products	98%, 50%, 10%
II	Concentrates Diluted into End Use Liquid Baits	1.2%, 0.5%, 0.14%
III	Concentrates Diluted into End Use Dry Baits	0.5%
IV	Concentrates Diluted into Registered Baits	0.5%
V	Ready-to-Use, End Use Dry Baits (meal, pellet, or block)	0.025%

Fumarin, a minor use pesticide that has a total yearly production of less than 5,000 pounds active ingredient (Kline, 1976), is an anticoagulant rodenticide, used as a dry bait in and around buildings and other structures and in transport vehicles (trucks, planes, and ships) for the control of Norway and Roof Rats and House Mice (commensal rodents). The Sodium Salt formulations are intended for use in liquid baits for the control of the same rats and mice, in the areas noted above. Most of the older labeling simply instructs the user to place baits in areas where rats and mice "feed, water or travel". A few labels also specify the use of Fumarin products in dumps. The baits are to be placed in locations not accessible to children, pets, livestock, or nontarget wildlife or be placed in tamper proof bait boxes.

Fumarin and its Sodium Salt are not mixed with other pesticides, although their baits may be used in conjunction with other rodenticides in a control program.

The methods of application for products containing Fumarin or its Sodium Salt are summarized below:

Type I. Technical (98%) and Concentrates (50%,10%) Formulated into Registered Products

These products are to be used only to formulate other registered products and, therefore, do not have application directions.

Type II. Concentrate(1.2%, 0.5%, 0.14%) Diluted into End Use Liquid Baits

These products, which all contain the Sodium Salt of Fumarin, are to be diluted with water to prepare a liquid bait containing 0.0125% active ingredient. The label specifies that the baits are to be applied in the following manner for control of commensal rats and mice:

a) For rats, up to 1 quart of bait solution is placed in shallow containers, chick founts, or special dispensers, where rats feed, water or travel. Bait is maintained at these locations for a minimum of 10 days.

b) For mice, up to 1 pint of bait solution is placed in shallow containers, chick founts, or special dispensers, set at 8 to 12 feet intervals where mice feed, water or travel. Bait is maintained at these locations for a minimum of 15 days.

Type III. Concentrates (0.5%) Diluted into End Use Dry Baits

These products are to be diluted (one part concentrate to 19 parts bait, by weight) with materials such as corn meal, rolled oats, meat, and fish to prepare an essentially dry bait containing 0.025% active ingredient. The label specifies that baits are to be applied in the following manner for commensal rats and mice:

a) For rats, 4 to 16 oz of bait is placed in dry, shallow containers at locations where rats feed, water or travel. Bait is maintained at these locations for a minimum of 10 days.

b) For mice, 0.25 to 0.5 oz of bait is placed in dry, shallow containers at intervals of 8 to 12 feet where mice feed, water or travel. Bait is maintained at these locations for a minimum of 15 days.

Type IV. Concentrates (0.5%) Diluted into Registered Baits

This product is to be used only to formulate other registered rodenticide baits. This type of product will not bear end-use application directions.

Type V. Ready-to-Use, End Use Dry Baits (0.25%)

These products, which are formulated as ready-to-use granular meal, pellets, or block, are to be used without dilution (ready-to-use) according to the generalized method of application. Directions for Type III Fumarin products, apply.

EXPOSURE PROFILE

Products of Fumarin and the Sodium Salt of Fumarin are available for use by commercial applicators and by homeowners in the form of dust and liquid concentrates as well as end-use dry formulations. The dust concentrate is diluted into end-use dry baits by mixing with materials such as oats, corn meal, meat or fish, and is placed in shallow containers for a minimum of ten days for the control of rats. Liquid concentrates are mixed with water and then placed in the same manner. There is a potential for dermal contact during preparation and placement of the end-use baits, particularly in the case of untrained or inexperienced users. Due to the extremely low potential for vaporization of either Fumarin or its Sodium Salt, and the coarse nature of the vehicle used for the dust concentrate, inhalation exposure is unlikely. Since the concentrates are mixed with edible substances and remain in place for several days, there is a potential for ingestion of the end-use baits by children and domestic animals, especially if use directions are not followed explicitly.

Technical Fumarin
Fumarin Solid Concentrate
Sodium Salt of Fumarin Solid Concentrate
Fumarin Solid Ready to Use

Technical Fumarin: For persons involved in the handling, storage, and shipment of Technical Fumarin, there is little likelihood of oral exposure. There is a possibility of both dermal and inhalation exposure, however, because this product is in the form of a powder.

Fumarin Solid Concentrate and Sodium Salt of Fumarin Solid Concentrate: For persons preparing baits by mixing the concentrate with an edible substance, there is a potential for dermal exposure because of contact with the active ingredient. There is also potential for exposure through ingestion of the baits, particularly by

children and domestic animals. Because the bait remains in place from 3 to 15 days, such ingestion could be repeated.

The potential for ingestion also applies to wildlife which have access to the bait areas, especially birds, small mammals, related rodents, or other animals which may frequent the treatment areas. Direct ingestion may occur as a result of contamination of the food web. Predators may eat exposed wildlife or the target animals.

Fumarin Solid Ready to Use: For persons handling the ready-to-use Fumarin products, there is little chance of exposure by ingestion or inhalation. Dermal exposure is possible, but is expected to be less likely than during mixing and subsequent placement of the concentrates. There is a potential for ingestion of the baits by children and domestic animals, especially if use directions are not followed explicitly.

The potential for ingestion applies as well to wildlife which have access to the bait areas, especially birds, small mammals, related rodents, or other animals which frequent treatment areas. Direct ingestion may occur as a result of contamination of the food web. Predators and domestic animals may be exposed by eating the target animal or exposed non-target wildlife (see Ecological Effects Chapter), especially if use directions are not followed explicitly.

TOPICAL DISCUSSION

Data usually required for the manufacturing-use chemical consists of hydrolysis and activated sludge metabolism studies as specified in Sections 163.62-7(b) and 163.62-8(g), respectively (43 FR, 29696). Data usually required for products intended for domestic outdoor applications are: hydrolysis, aerobic soil metabolism, field soil dissipation and absorption, as specified in Section 163.62-6(l). These data, however, do not generally apply to all classes of products. Use patterns of rodenticide products practically eliminate the kinds of potential hazards associated with insecticide, herbicides, or fungicide products use patterns.

Fumarin and its Sodium Salt are rodenticides which are used to control rats and mice in and around domestic dwellings, medical facilities, agricultural premises, ships, public transport vehicles, waste dumps, and commercial, industrial and public premises. Because of the low application rates (0.0021 oz. a.i./qt water, 1 pt/bait station and 0.004 oz. a.i./16 oz. solid bait, with bait stations every 10 feet) for domestic uses, the Agency does not expect that Fumarin residues will be in soil or water or will remain in the vapor state for any measurable period of time such that an assessment of potential re-entry hazard is necessary. Consequently, no data are required on the Environmental Fate of Fumarin or its Sodium Salt.

DISCIPLINARY REVIEW

Generic Data Gaps
Required Labeling

Generic Data Gaps

Because of the use pattern of Fumarin and its Sodium Salt, the limited poundage that is available and the small chance of residues being found in soil or water, Environmental Fate data are not needed to support the registration of products of Fumarin and its Sodium Salt.

Required Labeling

All technical and concentrated Fumarin products must carry the following warning on the label under the "Hazards to Wildlife" section:

> Do not discharge into lakes, streams, ponds, or public water unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the EPA.

Because of the potential for ingestion of baits by children and domestic animals, registrants are required to modify labels to require that baits be placed in inaccessible areas or be placed in tamper proof bait boxes as discussed in Chapter 2.

CHAPTER 5

RESIDUE CHEMISTRY

Fumarin and its Sodium Salt are used as rodenticides for the control of various species of rats and mice. These products have no food or feed use. Thus, there are no residue chemistry data requirements for Fumarin and the Sodium Salt of Fumarin. As a deterrant to its use around food and feed, label directions must include in the precautionary section the statement; "avoid contamination of food and feedstuffs and food handling surfaces."

CHAPTER 6

TOXICOLOGY

TOXICOLOGY PROFILE

Scientifically sound data on the toxicity of Fumarin and its formulated products are not currently available. A review of Fumarin's uses suggests, however, that exposure may occur. It it likely that oral, dermal, and inhalation exposure could occur because of Fumarin's use in and around homes, buildings, and farm buildings, however, repeated significant exposure is unlikely except for commercial applicators who use Fumarin routinely, especially in formulating baits from concentrates (see Environmental Fate discussion). Exposure to commercial formulators and applicators could be greatly reduced if protective clothing including gloves, long sleeves, and face masks are worn when handling Fumarin products.

The Agency's Proposed Guidelines (43 FR 163.81-.83) describe the toxicity data requirements needed by the Agency to determine the toxicity of pesticides to humans. Ordinarily separate studies are required for each end-use formulation. The Agency has determined that currently registered formulations of Fumarin are substantially similar in composition, differing only in form of the active ingredient - acid or sodium salt - and formulated with natural ingredients as inerts. Therefore, in most cases, toxicity data will be required for technical Fumarin and the 0.5% Fumarin concentrate only. Because of the great sensitivity of the eye to foreign substances, irritation testing will be required on technical Fumarin and some representative formulated products to ascertain effects on formulators exposed to the active ingredient and the dusts of the inert foodstuffs. The specific guidelines requirements are listed under the individual topical discussions that follow.

Technical Fumarin

Inadequate data were available to assess technical Fumarin's acute toxicology and irritation potential. Testing is required for acute oral, acute dermal and acute inhalation toxicity, primary eye irritation, primary dermal irritation and dermal sensitization. Additional testing is required with the 98% technical Fumarin only. Because inert ingredients are foodstuffs, testing is not required on 50 or 10 percent formulations. Toxicology tests from the 98% formulation will be representative and require only a 2 or 10 fold factor for extrapolation.

Data were not available to support an assessment of technical Fumarin's subchronic toxicity. Pest control operators who normally handle Fumarin and farmers who use it for rodent control in and around farm houses and barns are among the persons who may be repeatedly exposed to this

pesticide. The Agency, therefore, requires subchronic testing data so that the effects on mammals can be used to help assess the effects on humans in a similar manner. The test required is a 21-day subchronic dermal toxicity study. Subchronic inhalation testing will not be required because of extremely low potential for vaporization of Fumarin and Sodium Salt of Fumarin, coarse nature of the vehicle used for the dust concentrate, and because inhaled particles will be swallowed rather than cross lung alveolar space. Data were not available to support an assessment of any teratogenic potential of technical Fumarin. Testing is required.

Fumarin Solid Concentrate
Fumarin Solid Ready to Use

Data were not available to assess the acute toxicity and irritation potential of these types of formulations. Testing is required for acute oral, acute dermal and acute inhalation toxicity, primary eye, primary dermal irritation, and sensitization for the five Fumarin Solid Concentrates (0.5% concentrate). Primary eye irritation is required for the Fumarin Solid Ready to Use. Information from subchronic tests on the technical Fumarin will be adequate to assess potential effects to formulators. Subchronic testing is not required on these formulations because the exposure is expected to be mainly acute. Also, since both of the above formulations consist of active ingredient without chemical inerts, the results of acute tests with the solid concentrate (0.5% a.i.) will apply for the Solid Ready-to-Use products with 0.025% a.i. Primary eye irritation tests are not required if the pH is less than 3 or greater than 12.

Fumarin Sodium Salt Solid Concentrate

The Sodium Salt of Fumarin is not stable after ingestion because it dissociates rapidly in the stomach to Fumarin and sodium. Therefore, a separate set of toxicology feeding studies for Sodium Salt of Fumarin is not required. This applies to both technical material and formulations.

To assess the potential hazard from dermal or inhalation routes of exposure, an assumption cannot be made since the rate of dissociation of the sodium from the Fumarin under neutral pH is not known.

For formulators, inhalation of grain dust particles impregnated with the Sodium Salt of Fumarin will result primarily in oral exposure as the particles are swallowed rather than inspired. Little if any Sodium Salt of Fumarin is expected to reach alveolar space. Therefore, inhalation studies are also exempted.

The major anticipated exposure mode for the formulator would be dermal exposure. Because neither the dissociation

constant nor dermal toxicity studies on the Sodium Salt form exists, acute dermal toxicity studies or a dermal uptake kinetics study on the Sodium Salt form is required. However, if a salt dissociation study is performed to show that under pH conditions comparable to skin epidermis the Sodium Salt readily dissociates, the above tests will be waived and the effects will be assessed using the toxicology studies on Technical Fumarin.

In accordance with each of the data requirements (Data Gaps) listed below is the number of the sections in the "Proposed Guidelines" of August 22, 1978 (43 FR Part 163). The assessment of the toxic properties of the pesticides will be made by implementation of the minimum data requirements of the specified sections, unless otherwise stated under each section. Where no section number is listed, a minimum requirement has not been set for such information.

Data Gaps	Guidelines Section(s)
Acute Effects	163.81-1, -2, and -3
Local Irritation	163.81-4 and -5
Sensitization	163.81-6
Subchronic Effects	163.82-2,
Teratology	163.83-3
Mutagenicity	163.84-1, -2, -3, and -4

TOPICAL DISCUSSIONS

(Acute Effects)
Acute Oral Toxicity (163.81-1)

An acute oral toxicity study of technical Fumarin was conducted on rats resulting in an estimated LD_{50} of 0.4 gm/kg (Repole and Gee, 1954, 00001190). This study is insufficient to meet data requirements because of an improper testing protocol of using one animal per dose level by sex.

Technical Fumarin
Fumarin Solid Concentrate
Sodium Salt of Fumarin Solid Concentrate
Fumarin Solid Ready to Use

There are no data available for the assessment. Testing is required on the 98% technical and 0.5% concentrate.

Acute Dermal Toxicity (163.81-2)

Technical Fumarin
Fumarin Solid Concentrate
Sodium Salt of Fumarin Solid Concentrate
Fumarin Solid Ready to Use

There are no data available for assessment. Testing will be required on the 98% technical and 0.5% concentrate. Acute dermal toxicity studies on the Sodium Salt concentrate will also be required unless a salt dissociation study shows that the sodium salt form readily dissociates under pH conditions comparable to skin epidermis.

Acute Inhalation Toxicity (163.81-3)

Technical Fumarin
Fumarin Solid Concentrate
Sodium Salt of Fumarin Solid Concentrate
Fumarin Solid Ready to Use

There are no data available for assessment. Testing will be required on the 98% technical and 0.5% concentrate.

Primary Eye Irritation (163.81-4)

Technical Fumarin
Fumarin Solid Concentrate
Sodium Salt of Fumarin Solid Concentrate
Fumarin Solid Ready to Use

No data exist for assessment. Testing will be required on the 98% technical and 0.5% concentrate. Representative end use products containing 0.025% shall be tested. If the results of these tests indicate little or no irritation, no further studies are needed. If serious problems arise, all formualtions must be tested to assure proper labeling and safety to consumers and formulators. These tests are not required for products whose pH is less than 3 or greater than 12.

Primary Dermal Irritation (163.81-5)

Technical Fumarin
Fumarin Solid Concentrate
Sodium Salt of Fumarin Solid Concentrate
Fumarin Solid Ready to Use

There are no data available for assessment. Testing will be required on the 98% technical and the 0.5% concentrate.

Dermal Sensitization (163.81-6)

Technical Fumarin
Fumarin Solid Concentrate
Sodium Salt of Fumarin Concentrate
Fumarin Solid Ready to Use

There are no data available for assessment. Testing will be required on the 98% technical and 0.5% concentrate.

Subchronic Dermal Toxicity (163.82-2)

Technical Fumarin

There are no data available for assessing subchronic dermal toxicity of any Fumarin products. Testing will be required on the 98% technical since this is expected to be the principal route of exposure for formulators and users of concentrates.

Subchronic Oral Toxicity (163.82-1)
Subchronic Inhalation Toxicity (163.82-4)

Technical Fumarin

There are no data available for assessment. Testing will not be required of the low expected exposure from this route, considering both low volatility and type of formulations.

Teratology (163.83-3)

There are no data available for assessing the teratogenic potential of Fumarin. Anticoagulants have been associated with multiple congenital abnormalities in humans. Since exposure to females is possible, testing of the 98% technical in two mammalian species is required.

Mutagenicity (163.84-1,-2,-3 and -4)

Mutagenicity studies are required for Fumarin because Fumarin is approved for general use. Generally, mutagenicity data requirements cannot be waived on the grounds of minimal exposure resulting from protective clothing because mutagenic effects may result from a range of exposure levels, subacute to chronic, and protective clothing is generally efficacious in reducing acute exposures.

The following studies represent only the minimum requirements for data on the potential heritable effects of Fumarin.

1. A mammalian *in vitro* point mutation test.

2. A sensitive sub-mammalian point mutation test. (Bacteria, fungi, insect).

3. A primary DNA damage test (i.e., sister chromatid exchange or unscheduled DNA synthesis).

4. A mammlian *in vitro* cytogenetics test. If this test suggest a positive result, a dominant lethal or heritable translocation test may be required.

After results from these test systems and other toxicology disciplines have been considered, additional testing may be required to further characterize or quantify the potential genetic risks.

Although the Agency's mutagenic testing requirements are not final, the standards for these tests should be based on principles set forth herein (43 FR, No. 163, Tuesday, August 22, 1978). Protocols and choices of test systems should be accompanied by a scientific rationale. Substitutions of test systems for those listed above will be considered after discussion with the Agency.

The requirements should be considered an interim guide and not final Agency policy. However, the Agency does consider the above testing scheme to be a reasonable minimum requirement.

DISCIPLINARY REVIEW

Generic Data Gaps
Required Labeling

Generic Data Gaps

The following are gaps (data requirements) in the toxicology data base needed to adequately support a Registration Standard for Fumarin and its Sodium Salt. Listed after each gap is the section in the Proposed Guidelines of August 22, 1978 (43 FR, Part 163) that describes the type of data required. Under the heading, Data Requirments, is listed the type of Fumarin formulations for which data are required. Applicants must agree to provide or cite the required data and adhere to the noted label requirements for protective clothing as discussed in the Required Labeling Section of this chapter.

Category of Test	Data Requirement	Guideline No.
Acute Oral	An acute oral toxicity test on the rat is required for the 98% technical and the 0.5% concentrate.	163.81-1
Acute Dermal	An acute dermal toxicity study, preferably on the rabbit, is required for the 98% technical, and the 0.5% concentrate and the Sodium Salt concentrate.	163.81-2

Acute Inhalation	An acute inhalation test is required for the 98% technical and the 0.5% concentrate.	163.81-3
Primary Eye Irritation	A primary eye irritation test on the rabbit is required for the 98% technical, the 0.5% concentrate, and for representative end-use products containing 0.025%.	163.81-4
Primary Dermal Irritation	A primary dermal irritation test, preferably on the rabbit, is required for the 98% technical and the 0.5% concentrate.	163.81-5
Dermal Sensitization	A dermal sensitization test, preferably on the guinea pig, is required for the 98% technical and the 0.5% concentrate.	163.81-6
Subchronic Dermal	A 21-day subchronic dermal toxicity test in the rabbit for the 98% technical.	163.82-1
Teratology	Testing is required on the 98% technical Fumarin in two mammalian species.	163.83-3
Mutagenicity	Testing is required on the 98% technical Fumarin.	163.84-1, -2, -3, -4

Required Labeling

Labels must be changed to require persons (formulators, commercial applicators, and mixers) who handle technical Fumarin and concentrates to wear protective clothing including long sleeves, gloves, and face masks. The following precautionary statements should be included:

1. Wear protective clothing including long sleeves, impermeable hand gloves, and face masks when mixing and handling Fumarin products. Remove clothing and wash after handling.

2. Avoid contamination of food and feedstuffs. Do not place baits in contact with food and feedstuffs or on food handling surfaces.

3. Each label is required to have a section entitled, NOTE TO PHYSICIAN, because of possible ingestion of the bait, especially by children and domestic animals. This section shall have the following instructions:

   If swallowed by humans, domestic animals or pets, this material may reduce the clotting ability of the blood and cause bleeding. In such cases, intravenous and oral administration of vitamin K_1 combined with transfusion of fresh blood or fresh frozen plasma may be indicated as in the case of hemorrhage caused by overdose of bishydroxycoumarin.

4. Each label must include a first aid statement in the precautionary labeling section:

   If swallowed, call physician immediately.

BIBLIOGRAPHY

Kusano, T. 1969. Studies on the improved effectiveness of anticoagulative rodenticides on rodents: I. Synergistic toxic action between coumarin or indandione derivatives and thallium salts on mice. Journal of the Faculty of Agriculture, Tattori University 5:15-52.

Repole, J., and Gee, A.H. 1954. Toxicological testing of coumarin derivative on rodents and other animals. A report of Foster D. Snell, Inc., August 3, 1954. (Unpublished.)

CHAPTER 7

ECOLOGICAL EFFECTS

ECOLOGICAL EFFECTS PROFILE

Subpart E, Hazard Evaluation: Wildlife and Aquatic Organisms, of the Proposed Guidelines issued on July 10, 1978, describes the fish and wildlife data requirements needed by the Agency to assess the hazards of pesticides to nontarget organisms and to provide for adequate precautionary labeling.

In general, scientifically sound data on the toxicity of Fumarin® to non-target organisms is almost entirely absent. Available studies by Mendenhall and Pank, 1979 (GS-0004-001) and Pank and Hirata, 1976 (00032467) show that Fumarin can cause secondary poisoning in carnivores such as mongooses when fed to rats at field rates but does not appear to result in secondary poisonings to raptors such as barn owls. (see Topical Discussions below).

TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the sections in the Proposed Guidelines of July 10, 1978 (43 CFR Part 132) which explains the data the Agency would generally require to adequately assess Fumarin's hazard to the environment.

Data Gaps	Guidelines Sections
Birds	163.70-1, .70-4, .71-1, and .71-2
Wild Mammals	163.70-1, .70-4, .71-3 and .70-1(e)
Fish	163.70-1, .70-4, and .72-1
Aquatic Invertebrates	163.70-1, .70-4, and .72-2

These data will not be required to support use patterns covered by this Standard so long as the registrant modifies labels to require use with tamper proof bait boxes and only in or around buildings for outdoor and agricultural premises. For other registered uses, not including dumps, labels must be modified to require that baits be placed in tamper proof bait boxes, or in areas inaccessible to children, pets, and non-target wildlife. Should other significant uses be proposed or should registrants not wish to use required labeling, these studies may be required unless a logical argument can be made which shows minimal expectation of exposure and consequently, risk. Also, such studies may be needed if the total volume of use increases substantially.

Birds

The minimum data normally required to establish hazard to birds is a single-dose oral LD_{50} on one avian species, either a waterfowl (preferably mallard) or an upland game bird (preferably bobwhite or other native quail, or ring-necked pheasants) - the species shall be the same as one of two species selected for the avian dietary LC_{50}; a subacute dietary LC_{50} on two avian species, one waterfowl and one upland game bird (barn owl). No acceptable studies were available to meet these requirements.

One study was available on the secondary toxicity of Fumarin to birds. Mendenhall and Pank, 1979, (550304-001) fed 0.025% Fumarin (containing a total of 73.63 mg) mixed with oat groats to rats. The rats were then ingested by a barn owl, which survived. Although this study did not include a sufficient number of test animals, it suggests that secondary poisoning may not necessarily occur in barn owls feeding on Fumarin treated rats at field rates.

Wild Animals

The minimum data normally required to establish the toxicity to wild mammals are a primary dietary LC_{50} on carnivores (preferably a mustelid or small canid); and a secondary toxicity feeding study on carnivores (preferably a mustelid or small canid).

No acceptable primary study was available to meet the requirement. One study was available on the secondary toxicity of Fumarin to wild mammals. Pank and Hirata, 1976 (00002467) mixed technical Fumarin with oat groats, and fed this formulation to rats. One mongoose which ingested 3 rats for a total dosage up to 31.2 mg, survived. Mongooses which ingested 6 rats (which were fed a total dosage of 47.8 mg) and 7 rats (which were fed a total dosage of 56.9 mg) did not survive. This suggests that Fumarin can cause secondary poisoning to carnivores such as mongooses when it is fed to rats at field rates. It is inadequate for concluding the toxicity to mammals due to an insufficient number of test animals (see Toxicology, Chapter 6).

Although no acute or subacute oral, dermal or dietary data are available on rats or wild mammals, this information suggests that Fumarin is at least highly toxic to wild mammals.

Fish

The minimum data normally required to establish toxicity of Fumarin to freshwater fish is a 96-hr LC_{50} test on a coldwater species (preferably rainbow trout) and a warmwater species (preferably bluegill). No acceptable fish studies are available to meet these requirements.

Aquatic Invertebrates

The minimum data normally required to establish toxicity of Fumarin to aquatic invertebrates is an acute LC_{50} either for 48-hr on first instar daphnids, or for 96-hr on early instar amphipods, stoneflies or mayflies. No acceptable aquatic invertebrate studies were available to meet this requirement.

DISCIPLINARY REVIEW

Ecological Effects Hazard Assessment
Generic Data Gaps
Required Labeling

Ecological Effects Hazard Assessment

Formulated Products Containing Fumarin

The hazard to aquatic organisms and wildlife from Fumarin products is expected to be minimal because of the low volume of use and method of application. It is common practice for major exterminators to rotate rodenticides to reduce bait shyness and chance for tolerance buildup by target rodents. The less than 5,000 pounds of Fumarin active ingredient produced annually are not only of low volume usage, but are applied only in spot locations.

Despite the absence of data, it is possible to logically pursue the expected exposure and hence significance of risks to wildlife and fish. Aquatic exposure is unlikely given the use patterns, and low total use of the compound. Sodium salts, while more soluble, are not expected to cause significant risks even when used as liquids because of the use pattern, location relative to water, and quantities.

It is expected that if there is a spill of the 0.0021 ounces of the Sodium Salt of Fumarin every ten feet and the leaching of 0.004 ounces of Fumarin from solid bait every 10 feet, neither ground water or bodies of water would be burdened because of the small amount of material going into the ground. In addition, application directions do not provide for applying Fumarin or its Sodium Salt to bodies of water. On the contrary, outside application of Fumarin is to be placed immediately around buildings (within 5 feet).

Avian hazard can result from two sources, direct ingestion of baits or liquids and through secondary poisoning by consumption of poisoned rodents. Non-target mammals are also susceptable to such poisons. Exposure to the first type of risk can be reduced by making the bait, when used for outdoor and agricultural purposes, less accessible to non-target species through use of appropriate bait boxes (for both liquids and solids) and placement. For other uses, not including dumps, risk can be reduced by use of bait boxes or by placing baits in areas inaccessible to children, pets, and non-target wildlife. To

reduce the hazard of secondary poisoning, label changes could require proper disposal of dead animals.

If registrants want to use these products in dumps, or any place not immediately around buildings, Ecological Effects data will be needed to fully assess the hazard of Fumarin and its Sodium Salt to fish and wildlife.

Generic Data Gaps
Technical Fumarin and Its Sodium Salt

Ordinarily six basic and one conditional study would be required to provide a toxicological profile on fish, birds, and aquatic invertebrates. This profile enables the Agency to write precautionary labeling and assess environmental hazards for all products covered by this Standard. Since Fumarin is a minor use pesticide, these studies will not be required. Should yearly production of Fumarin and its Sodium Salt reach 25,000 pounds, the studies discussed above may be required to support the continued registration of these pesticide products.

Formulated Products containing Fumarin and its Sodium Salt

Usually data supplied on technical material is sufficient to support formulated products.

These data will not be required to support use patterns covered by this Standard so long as the registrant modifies labels to require use with tamper proof bait boxes and only in or around buildings. Should other significantly different uses be proposed or should registrants not wish to use required labeling, these studies may be required unless a logical argument can be made which shows minimal expectation of exposure and consequently, risk.

Required Labeling

Manufacturing Use

Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the EPA.

Formulated Products:

Bait Placements: For outdoor and agricultural premises, liquid and solid baits are to be placed in tamper proof bait boxes. For other uses, excluding dumps, baits must be placed in tamper proof bait boxes or in areas inaccessible to children and non-target birds and mammals. These bait boxes should be placed at 8 to 12 feet intervals and/or at sites where rodents congregate. For exterior building placement, bait is to be stationed around (within 5 feet of building outer walls) exterior surfaces only, and not in fields adjacent to buildings.

CHAPTER 3

REGULATORY RATIONALE

A. REGULATORY DECISION

The Agency has determined that products of Fumarin[R] and the Sodium Salt of Fumarin can be Federally registered for United States sale and distribution. Data are not available which would indicate that Fumarin or its Sodium Salt meet any of the risk criteria for unreasonable adverse effects as listed in 40 CFR 162.11(a) [Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing]. To be covered under this standard, applicants must agree to submit or cite the data and adhere to labeling requirements listed in Chapter II of this document. In some cases, registrants have a choice between submission of data or modification of labels as discussed in the individual Chapters. Labels also must conform to the general sample labels distributed by the Registration Division.

B. PRODUCT COMPOSITION

The Agency will consider for registration products which contain any percentage of Fumarin or its Sodium Salt as an active ingredient (a.i.). The Agency expects most technical material to be 98% a.i. Should an applicant desire to register products that depart greatly from those currently registered, that applicant should contact the Agency for specific directions on how to register those products.

C. RATIONALE FOR LABELING REQUIREMENTS

Since most of the data needed to assess the hazard of Fumarin products does not now exist, the Agency's immediate efforts at risk reduction center on updating the product labeling to clarify the sites, pests, and methods of application; revising out-of-date precautionary and storage/disposal statements; and placing label text in a clear, readable format. Such labeling modifications are being required in order to reduce any hazards associated with Fumarin products.

D. RATIONALE FOR DATA REQUIREMENTS

1. Product Chemistry

The Federal Insecticide, Fungicide, and Rodenticide Act Section 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States, including general chemistry requirements (EPA,

1973a). The Agency requires data and information specifically on the manufacturing and formulation processes, analytical methods, and on the formation of manufacturing impurities and other product ingredients in order to establish the composition of products proposed for registration. Data on the physical and chemical properties also are required of all formulations. The Agency uses these data to characterize each pesticide and to help determine the environmental and health hazards of the pesticide.

2. Environmental Fate

Environmental Fate data are not needed because usage of Fumarin and its Sodium Salt are not broadcast. Instead, usage is localized and is only in spot locations. Baits are protected from rain or snow, and are therefore not expected to affect any crops or ground water.

3. Toxicology

Data on the toxicity of Fumarin and its formulated products are not currently available. A review of Fumarin's uses suggest, however, that some exposure can occur on an acute or subchronic basis because of its uses in and around homes, buildings, and farm buildings, although it is generally expected to be low. Data, therefore, are needed by the Agency to determine the toxicity of Fumarin to humans. Ordinarily, separate studies would be required for each end-use formulation. The Agency has determined, however, that because currently registered end-use formulations of Fumarin are substantially similar in composition, in most instances, toxicity data will be required for technical Fumarin and the 0.5% Fumarin Concentrate only. Data generated from these formulations will be used to extrapolate to the toxicity of the other formulated products. The exception to toxicity extrapolation is in the assessment of eye irritation potential where testing will be required for the technical Fumarin, the 0.5% Fumarin concentrate, and representative end-use products. Normally, testing would be required on all formulations, but because of the similarities of these end-use formulations, testing will be only required on some typical products.

4. Ecological Effects

In general, scientific data on the toxicity of Fumarin to non-target organisms are entirely absent or inadequate. Two available studies Pank and Hirata, 1976, (00002467) and Mendenhall and Pank, 1979 (GS0004-001) show that Fumarin can cause secondary poisoning in carnivores when fed to rats at field rates. The Agency has determined, however, that fish

and wildlife studies are not required because of the use pattern of these pesticides, the relative low volume of use of these pesticides and the small chance of residues being found in water or soil. The Agency, therefore, is instead requiring labeling changes for products covered by this standard to reduce and/or eliminate hazard to fish and wildlife. Registrants desiring to use this pesticide in dumps or in areas not in or around buildings may be required to submit the data.

E. RATIONALE FOR EFFICACY DATA REQUIREMENTS

The Agency is not including these data as part of the Standard because the data must be formulation specific.

The Agency's current policy is to require efficacy data to support public health uses. A public health use exits whenever the continued presence of the target pest organisms may pose a threat to human health, either by direct action or through transmittal of disease. Such uses include commensal rat and mouse products. Therefore, data would be required to support the uses contained in this Standard.

The effectiveness of products containing Fumarin and its Sodium Salt covered by this Standard depends upon many factors. (Palmateer, 1974, 05001803; in press, G). These factors include impurities in the technical; contamination of the product with other pesticides during manufacture and storage; type, quality, hardness, and particle size of inerts added to the technical and concentrates; and the test procedures. The efficacy of products with the same percentage of active ingredient can vary dramatically since efficacy is a function of bait acceptance. For these reasons, standardized laboratory testing on each specific formula is required.

For guidance on testing products, registrants are referred to Subpart G of the Guidelines, the Agency's Manual of Test Methods (EPA, 1977).

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into 3 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard, (2) citations examined and judged to be inappropriate for use in developing the standard, and (3) standard reference material. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations, and should be called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards for the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identificable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

   b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parenthesis. For studies submitted to us in the past, the trailing parenthesis include (in addition to any self-explanatory text) the following elements describing the earliest known submission.

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission ofo the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alpnabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting Registrations Under the Standard

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Citations Examined and Judged to be Inappropriate For Use in Developing the Standard

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